

**DECLARATION OF MITCHELL F. BRIN**  
**(37 C.F.R. section 1.132)**

I Mitchell F. Brin declare as follows:

1. I am a citizen of the United States and presently reside in Newport Beach, California.

2. I am over the age of twenty one, competent to testify in a court of law, and could and would testify to the matters set forth below before the United States Patent and Trademark Office, if required to do so.

3. I understand that this declaration will be used to assist prosecution of one or more of the following related patent applications:

(1) United States patent application serial number 10/933,723, including to assist to overcome a rejection in the December 15, 2006 office action in serial number 10/933,723;

(2) United States patent application serial number 10/443,593, including to assist to overcome a rejection in the November 13, 2006 office action in serial number 10/443,593;

(3) United States patent application serial number 10/726,904, including to assist to overcome a rejection in the December 15, 2006 office action in serial number 10/726,904;

(4) United States patent application serial number 10/460,898, including to assist to overcome a rejection in the November 13, 2006 office action in serial number 10/460,898, and;

(5) United States patent application serial number 10/461,829.

4. I graduated from the University of Pennsylvania in 1975 with a bachelor of arts in biology (Magna Cum Laude and Phi Beta Kappa) and I received an M.D. degree from the Columbia College of Physicians and Surgeons in 1979. I was a medical intern at the Mount Sinai Hospital and School of Medicine from 1979 to 1980. I was a neurology

resident from 1980 to 1983 at the Neurological Institute of the Presbyterian Medical Center of New York City and I was a Fellow at the Columbia University Neurological Institute from 1983 to 1986, carrying out research on the treatment of movement disorders with botulinum toxins. During the period of 1986 through 1994, I was an Assistant Professor of Clinical Neurology and Assistant Professor of Neurology at the Columbia University College of Physicians and Surgeons. At this time, I also served in the capacity of the Coordinator of the Dystonia Clinical Research Center.

5. In 1994, I joined the Mount Sinai Medical Center and School of Medicine as an Associate Professor and Director of the Movement Disorders Program where I continued my professional activities through 2000. I also served as Director of Movement Disorders and held the Bachmann-Strauss Endowed Chair in Neurology. I continue as an Adjunct Professor of Neurology at the Mount Sinai School of Medicine and became a faculty member at the University of California, Irvine, School of Medicine in 2002, as a Clinical Professor of Neurology.

6. I founded the American Academy of Neurology course on botulinum toxin, and I have organized numerous courses and symposia on botulinum toxin, and published extensively on the subject of therapeutic use of the botulinum toxins.

7. I am Founder and Past President of WE MOVE (Worldwide Education and Awareness in Movement Disorders) which is an international professional and patient educational not-for-profit organization that focuses on movement disorders. I also serve on the board of directors of the Bachmann-Strauss Dystonia and Parkinson Foundations and have served on the Board of the Exceptional Parent Foundation. I serve on the Executive Committee of the United States Pharmacopeial Convention (USP) Council of Experts, and I am the Chair of the Neurology, Otolaryngology and Ophthalmology Expert Committee of the USP. I am a member of: the American Academy of Neurology Section on Movement Disorders and Co-Founder of the Dystonia Study Group; the United States Interagency Botulism Research Coordinating

Committee, and; the University of California, Irvine, Dean of Biology's Leadership Council.

8. I have served on the editorial and peer-review boards of numerous scientific journals and on the steering committee of the World Congress on Disabilities. I am a Fellow of the American Academy of Neurology; a recipient of the FDA Commissioner's Special Citation for work with neurological movement disorders; and a recipient of the Distinguished Service and Honor Award from the American Academy of Otolaryngology-Head & Neck Surgery.

9. I was one of the first investigators to examine the use of botulinum toxin for the treatment of medical disorders and I pioneered the use of botulinum toxin for the treatment of dystonias, including blepharospasm and other debilitating neurological disorders. I have designed and conducted double blind studies examining the use of botulinum toxin for numerous conditions and have conducted numerous multicenter studies for uses of botulinum toxin.

10. Over the course of my career, I have received research funding from numerous public (e.g., National Institutes of Health, Food and Drug Administration) and private sources (e.g., not-for-profit patient Foundations, Industry grants, etc.) to further an understanding of medical disease, development of therapeutics, conduct clinical trials, and provide education about medical illnesses. Specific to the study of botulinum toxin, I have been funded by the Dystonia Medical Research Foundation, National Institutes of Health, Food and Drug Administration, Bachmann-Strauss Foundation, Allergan Inc., Athena Neurosciences, and Ipsen Pharmaceuticals. Specifically with regard to Allergan Inc., beginning in about 1990 I received several unrestricted medical grants to study various therapeutic uses of Botox® (Botulinum toxin type A purified neurotoxin complex). Additionally, between 1997 and 2000 I attended a number of Botox® advisory board and technology update meetings sponsored by Allergan and signed confidential disclosure agreements so that I could participate in these meetings.

11. Since about 1984 (including during 1993) I have diagnosed and treated many patients with botulinum toxin to treat a variety of disorders and conditions including hyperhydrosis, cervical dystonia (spasmodic torticollis), tardive dyskinesia, essential tremor, spasmodic dysphonia, smooth muscle spasm, temporal mandibular disorder, muscle spasm pain (including smooth muscle spasm pain), spasticity, swallowing disorders, and headache, including migraine headache and tension headache. I have administered different serotypes of botulinum toxin to patients.

12. A partial list of my publications is attached to this declaration as Attachment 1. These publications include Jankovic J, and Brin M., *Therapeutic Uses of Botulinum Toxin*, New Eng J. Med, 1186-1194;1991, which is cited on page 2 of each of the five pending patent applications cited in paragraph 3 above.

13. By training and experience I am an expert in the therapeutic use of the botulinum toxins.

14. I have been an employee of Allergan, Inc. of Irvine, California ("Allergan") since January 2001. My current position with Allergan is Senior Vice President, Development and Therapeutic Area Head, Botox® and Neurology. In this position I oversee the Botox® development portfolio, and direct clinical programs for uses of botulinum toxin. Allergan is the assignee of the patent applications cited in paragraph 3 above, as well as of their common parent application, U.S. application serial number 08/173,996, which has a filing date of December 28, 1993 and which is referred to hereafter as "the '996 application".

15. I have read the '996 application and in my opinion a physician of ordinary ability with knowledge of or experience using a botulinum toxin (the "Physician") would in December 1993 have very clearly realized upon reading the '996 application that the '996 patent application describes methods for treating at least hyperhydrosis, cervical dystonia, tardive dyskinesia, essential tremor, spasmodic dysphonia, smooth muscle spasm, temporal mandibular disorder, muscle spasm pain, including smooth muscle

spasm pain, spasticity, swallowing disorders, and headache (the Disorders") by administration of just the neurotoxic component of a botulinum toxin complex to a patient with one or more of the Disorders.

16. I base my opinion in paragraph 15 above on the following facts:

(1) page 3, lines 5-24 of the '996 application discloses that:

- (a) there is a neurotoxic component of a botulinum toxin;
- (b) the neurotoxic component has a molecular weight of about 150 kD;
- (c) the 150 kD neurotoxic component can be in the form of a dichain, that is comprising a 50 kD short chain and a 100 kD long chain, and;
- (d) the neurotoxic component is responsible for the toxic properties of a botulinum toxin.

(2) the matters set forth in paragraph 16(1) (a) to (d) above were also facts already established in the literature and therefore known to the Physician. See for example page 6 of Simpson L., *Current Concepts of the Mechanism of Action of Clostridial Neurotoxins*, in DasGupta B., Botulinum and Tetanus Neurotoxins, Plenum Press, New York (1993) (attached as Attachment 2), and; page 82 of Schantz E., et al., *Properties and use of botulinum toxin and other microbial neurotoxins in medicine*, Microbiol Rev 1992 Mar;56(1):80-99 (attached as Attachment 3).

(3) significantly, page 3, lines 5-24 of the '996 application discloses that use of the neurotoxic component (in either it's single or dichain forms) is "useful in the method of the present invention" thereby directly and immediately telling the Physician that the neurotoxic component can be used to treat the Disorders.

(4) on page 5, at lines 16-21 of the specification it is disclosed that a botulinum toxin is a zinc endopeptidase. The Physician would readily understand this to mean that it is the neurotoxic component of a botulinum toxin that is the zinc endopeptidase, and this is taught by the literature as well. See for example Schiavo G., et al., *Botulinum*

*Neurotoxins are Zinc Proteins*, J Biol Chem 1992 Nov; 267(33): 23479-83 (attached as Attachment 4).

17. It is also my opinion that the Physician upon reading the '996 application in December 1993 would have been able with little or no difficulty to obtain the neurotoxic component of a botulinum toxin so as to be able to use the neurotoxic component to treat a patient with one or more of the Disorders.

18. I base my opinion in paragraph 17 above on the following facts:

(a) the '996 application states on page 4, lines 9-12 that a botulinum toxin can be purified in accordance with known techniques. It was known to the Physician in 1993 that the neurotoxic component of a botulinum toxin could be obtained by running a botulinum toxin complex through a protein separation resin (such as a Sephadex gel) in an alkaline pH buffer. See for example Wagman J. et al., *Botulinum Type A toxin: properties of a toxic dissociation product*, Arch Biochem Biophys 1953; 45: 375-383 (attached as Attachment 5); DasGupta B., et al., *Separation of toxin and Hemagglutinin from crystalline toxin of Clostridium botulinum type A by anion exchange chromatography and determination of their dimensions by gel filtration*, J Biol Chem 1968 Mar 10; 243(5): 1065-72 (attached as Attachment 6); Schantz E., *Use of crystalline type A botulinum toxin in medical research*, being pages 143-150 of in Lewis G., *Biomedical aspects of botulism*, Academic Press, New York (1981, page 143 (attached as Attachment 7); Borodic, G., et al., *Clinical and scientific aspects of botulinum A toxin*, Ophthalm Clinics of N America 1991 Sep; 4(3): 491-503 (attached as Attachment 8), and; Schantz (1992) (Attachment 3). Thus, it was well known to the Physician, as indicated by the '996 application, that the neurotoxic component could be purified from a botulinum toxin complex

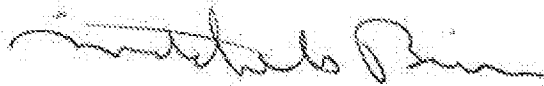
(b) additionally, it was known to the Physician that the neurotoxic component of a botulinum toxin was available for purchase simply by ordering it from a commercial supplier, such as Sigma.

(c) the '996 application gives particulars as to how a physician can administer the neurotoxic component on pages 7-8 of the specification (in the Detailed Description section of the specification) and the Physician would be aware of techniques for administration of the neurotoxic component, such as by intramuscular or subcutaneous administration.

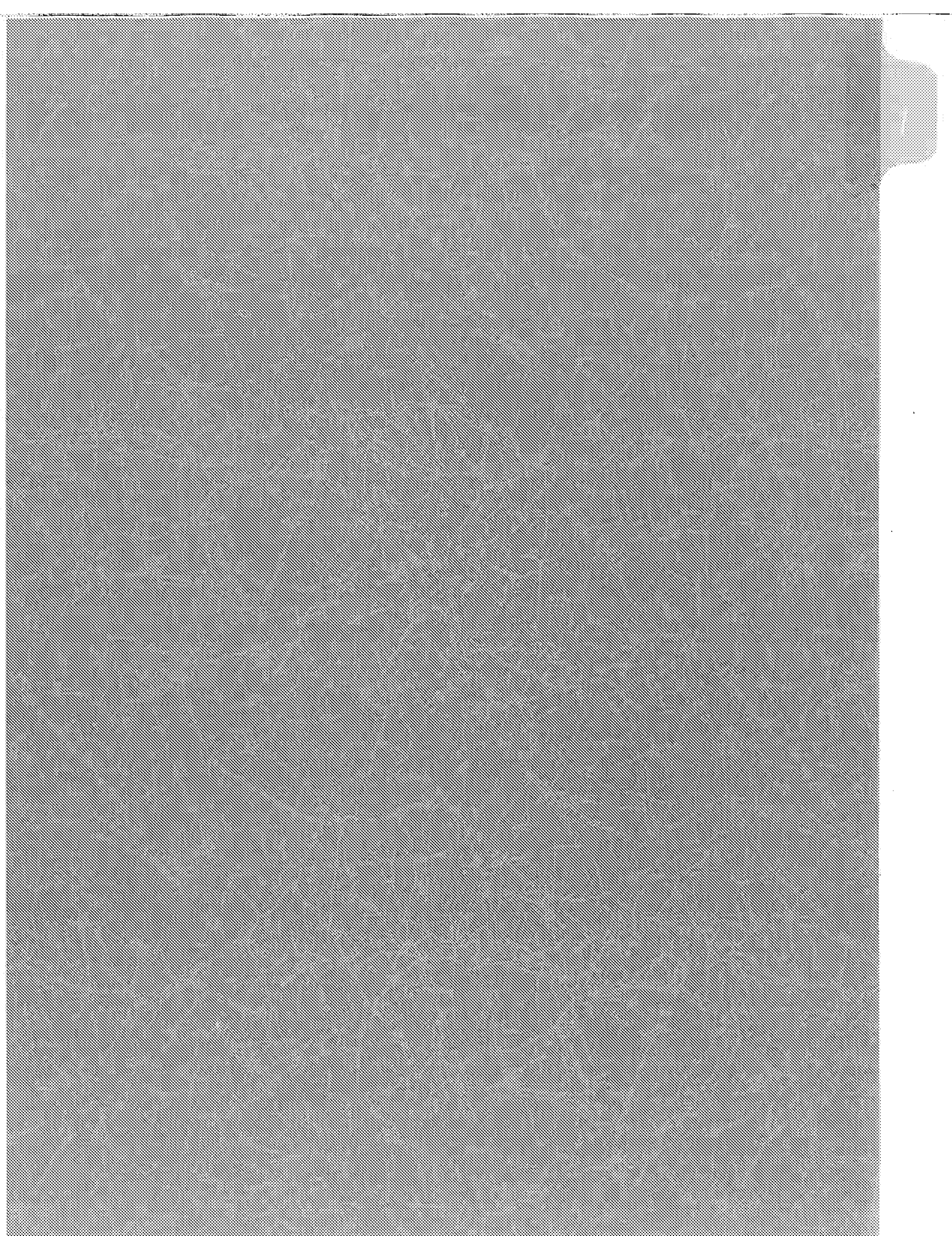
19. To reiterate, it is my opinion that the Physician after reading the '996 application would have very clearly realized that the '966 application sets forth methods for treating a patient afflicted with one or more of the Disorders using the neurotoxic component of a botulinum toxin, and that the Physician would have been able to easily proceed to treat a patient suffering from a Disorder with the neurotoxic component of a botulinum toxin based on the disclosure and guidance provided in the '996 application.

20. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity and/or enforceability of the instant patent application or any patent issuing thereon.

Executed this 28<sup>th</sup> day of March 2007 in Irvine, California.



Mitchell F. Brin





## Mitchell F. Brin, M.D

### PUBLICATIONS:

#### A. Original, Peer Reviewed Reports:

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2. Dr. Brin is President of WE MOVE ([www.wemove.org](http://www.wemove.org)), and is contributor/editor for the entire website. This includes the content and slide series (downloadable) on dystonia, Parkinson's disease, tics/Tourettes, myoclonus, tremor and spasticity.
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